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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,581	10/23/2001	John H. Stevens	HRT-287	4692

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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12/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/047,581	Applicant(s) STEVENS, JOHN H.	
	Examiner CHRISTOPHER D. PRONE	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20,23,25-32 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20,23,25-32 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 15-20, 23, 25-32, and 42-44 are pending.

Claims 1-14, 21, 22, 24, and 33-41 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20, 23, 25-32, and 42-44 and are rejected under 35 U.S.C. 103 as being unpatentable over Ersek USPN 3,657,744 in view of Lazarus et al. USPN 5,562,728.

Ersek discloses the invention substantially as claimed being a valve comprising a flexible sleeve (the outer portion of the valve sutured to the support) having 3 cusps 46, and a balloon expandable ring attached to the outside of its proximal end wherein the sleeve is not inverted shown best in figures 4 and 8. In regards to the ring, Ersek discloses a plurality of zigzag shaped support rings that each are shorter than the length of the sleeve. Ersek further discloses that the heart valve can be positioned at a variety of positions at the end of the device. This would allow one zigzag portion to be positioned according to the applicant's invention.

However, Ersek does not disclose a fastener member extending from the ring comprising a pair of legs with sharp ends.

Lazarus teaches the use of a support comprising a plurality of fasteners 151 attached to a zigzag shaped ring comprising a pair of legs having sharp ends (Figures 11-13) in the same field of endeavor for the purpose of piercing and anchoring the device into the surrounding tissue.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the fasteners taught by Lazarus with the device of Ersek in order to provide better attachment to the implant site.

Response to Arguments

Applicant's arguments filed 10/11/10 have been fully considered but they are not persuasive. The applicant argues that the combination fails to disclose at "least one ring attached to the outside surface at only the proximal end of the sleeve". However considering the claims in light of the broadest reasonable interpretation, the combination does disclose all of the claimed structural components. The applicant argues that Ersek discloses rings at both the proximal and distal ends unlike their invention which has only rings at the proximal end. This is not persuasive because the claim does not require there to not be a ring at the distal end. The claim simply requires "at least one ring" that is "attached at only the proximal end." The rings at the proximal end of Ersek are only attached at the proximal end because it does not extend to the distal end. The ring at

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the distal end is irrelevant to the claim language because the implant discloses separate proximal end rings.

However in order to advance prosecution the applicant is advised to amend the claims to limit the structure to **only have 1 ring and to better define the length of the sleeve.**

The applicant also argues that the combination is inappropriate because the use of the Lazarus reference is based on improper hindsight and the examiner's use of official notice. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Additionally it is unclear why the applicant thinks that the examiner is taking official notice. Nowhere in the rejection was any case law or statements of official notice provided by the examiner. The rejection included the facts disclosed by Ersek, the deficiency of Ersek, the facts disclosed by Lazarus, that both references are in the same field of endeavor, and a motivation for combining the references. This is a proper format for a 103 rejection without any official notice. The combination is supported factually by each disclosure and with the motivation for providing better attachment to the implant site.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738